

FSMA Rule 204
Implementation
Toolkit



FSMA Rule 204 Implementation Toolkit



Members of the food industry and technology solution providers should align on a common language to help stakeholders meet the U.S. Food and Drug Administration's (U.S. FDA) Food Safety Modernization Act Rule 204 (FSMA Rule 204) requirements in an interoperable, scalable, and efficient manner.



GS1 US is here to help! This comprehensive toolkit includes information and resources that will:

- Inform you and your customers about key FSMA Rule 204 requirements and how to prepare for them.
- Explain how to integrate GS1 Standards into your traceability solutions.





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to learn more and use the navigation buttons in the top right to jump forward and backward throughout the toolkit.







Executive Summary



FSMA RULE 204: EXECUTIVE SUMMARY 1 OF 3

Prepare to Meet FSMA Rule 204 Requirements and Gain Supply Chain Visibility

The compliance deadline for the requirements of the Food Safety Modernization Act, section 204(d), is **January 20, 2026**. It is critical for organizations to start their implementations and benefit from adopting GS1 Standards.

Targeted, precise recalls reduce the impact, duration, and risk of foodborne illness outbreaks. Each year, 48 million people get sick from foodborne diseases in the U.S. The yearly average cost of recalls in the U.S. is **\$10 million**. GS1 Standards can help improve your recall management and meet regulatory requirements by enabling traceability.*



WHY GS1 STANDARDS

"Traceability is vital to food safety, establishing the legality of ingredients and validating sustainability. GS1 Standards provide the framework for all of it."

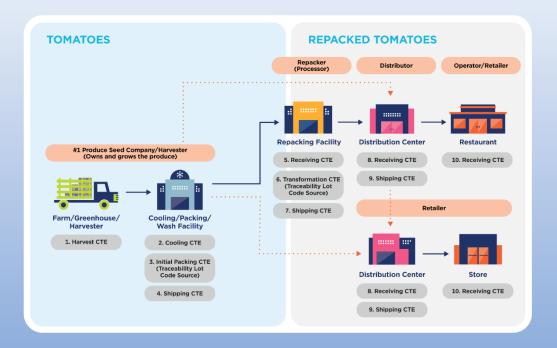
- Renée Perry, Vice President, Culinary Collaborations

^{*}Source: https://www.cdc.gov/foodborneburden/index.html



FSMA RULE 204: EXECUTIVE SUMMARY 2 OF 3

Many Stakeholders, One Goal



Retailers, operators, distributors, manufacturers, solution providers, and associations align on leveraging GS1 Standards across the supply chain to help meet FSMA Rule 204 requirements.

How do you enable traceability and visibility along the supply chain?

By recording standardized Key Data Elements (KDEs) at Critical Tracking Events (CTEs) along a product's journey.



FSMA RULE 204: EXECUTIVE SUMMARY 3 OF 3

ROI Beyond Compliance

Information

- Accurate information drives sales
- Clean data saves time, money, and resources

Product

- Less product waste
- · Ability to better identify affected lots for recall
- Better freshness management

Process

- Greater efficiency/transparency via automation
- Enhanced consumer and patient safety

Consumer Engagement

- Brand loyalty
- Additional safety







Basics for the Rule



FSMA RULE 204: BASICS FOR THE RULE 1 OF 3

Overview

What is it and who is impacted?

- Final FSMA Rule 204 on Requirements for Additional Traceability Records for high-risk products are outlined in the Food Traceability List (FTL).
- Anyone who manufactures, processes, packs, holds foods on the FTL, including foreign and domestic entities.
- Full and partial exemptions may apply.

What is required?

- Must keep records on foods from Farm to Store/Restaurant by production Lot.
 Supply chain partners need to share records.
- Provide Critical Tracking Events (CTEs) and Key Data Elements (KDEs) to U.S. FDA within 24 hours.
- Must keep a documented Traceability Plan.

When?

- FINAL rule effective: January 2023
- Compliance date: January 20, 2026
- **Records** should be maintained for 2 years.





FSMA RULE 204: BASICS FOR THE RULE 2 OF 3

Food Traceability List



Cheese (other than hard cheeses)



Crustaceans (fresh and frozen)



Cucumbers (fresh)



Finfish (fresh and frozen)



Fruit (fresh cut)



Herbs (fresh)



Leafy Greens (fresh)



Leafy Greens (fresh cut)



Melons (fresh)



Molluscan Shellfish Bivalves (fresh and frozen)



Nut Butters



Peppers (fresh)



Ready-to-Eat Deli Salads (refrigerated)



Sprouts (fresh cut)



Shell Eggs (fresh)



Smoked Finfish (refrigerated and frozen)



Tomatoes (fresh)



Tropical Tree Fruit (fresh)



Other Than **Leafy Greens** (fresh cut)





FSMA RULE 204: BASICS FOR THE RULE 3 OF 3

Critical Tracking Events & Key Data Elements



U.S. FDA's definition of CTEs and KDEs

Critical Tracking Events (CTEs)

are activities in the supply chain that must be recorded by the capture of key information about a business step for product movement in the supply chain. Typically, these events involve a product's transformation, shipping, or creation.

Key Data Elements (KDEs) are the attributes that describe/support the critical tracking event; this data answers the What, Where, When, Who, and Why of the event.





Toolkit Central





REQUIREMENTS

Overview

REQUIREMENTS	3010110113				
Identify FTL Items & Product Description KDEs	GTIN and GDSN ►				
Parties & Locations Description KDEs	GLN and GS1 US Data Hub >				
Shipping KDEs	ASN (EDI 856)*≻				
All Other CTEs/KDEs	EPCIS >				
Capture TLC (Traceability Lot Code) & TLC Source Throughout Supply Chain	Data Carriers, ASNs, EPCIS >				
Connecting Master Data to Transactional and Event Data ▶					

SOLUTIONS

*Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information refer to x12.org/products/transaction-sets



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FSMA RULE 204: TOOLKIT CENTRAL

GTIN and GDSN 10F2

- **GTINs (Global Trade Item Numbers)** can be used to identify trade items that are in scope for FSMA Rule 204 that are:
 - Part of the U.S. FDA's Food Traceability List (FTL).
 - Contain ingredients that are on this list and have not undergone a kill step.
- **GTINs** can be included in the transactional (Advance Ship Notices—ASNs) and event (Electronic Product Code Information Services—EPCIS) data to point to the rest of the product information in a Master Data System.
 - See <u>"Connecting Master Data to Transactional and Event Data"</u> for more info.
- GDSN® (Global Data Synchronization NetworkTM) can be used to share all Product Description Key Data Elements (KDEs) required by FSMA Rule 204.



Using GTIN and GDSN 20F2

Identify FTL Items

Section 3.3.3 of the GS1 FSMA Rule 204 **Guideline** specifies the two GDSN attributes that are available to identify items in scope for FSMA Rule 204:

- RegulationTypeCode = TRACEABILITY_REGULATION
- U.S. Local Code Value for regulatory Act (BMS ID 3071) = FSMA204
- Two other field to specify why not covered: KILL STEP APPLIED OR NOT COVERED BY FTL

Product Description KDEs

Section 4.3 of the GS1 FSMA Rule 204 **Guideline** specifies mappings between the product description KDEs required by the Final Rule and attributes in GDSN.

Example of GTINs for Traceability Product Descriptions and Traceability Product Identifiers

GTIN OR OTHER PRODUCT IDENTIFIER	BRAND NAME	COMMODITY	VARIETY	PRODUCT NAME	PACKAGING SIZE	PACKAGING STYLE
00614141007349	Brand ABC	Tomatoes	Cherry	n/a	25 LB	Carton
00614141004366	Brand ABC	n/a	n/a	Sprout Mix	4 oz	Clamshell
10012345000055	Brand 123	Tuna	Atlantic Bluefin	n/a	10 KG	Bin
80498265800736	Brand XYZ	N/A	N/A	Queso Fresco	12 x 8 oz	Vac Pack
105146287231822	Brand 999	N/A	N/A	Small Vegetable Tray w/ dip	6 oz	Tray
107483945748382	Brand 111	N/A	N/A	Peanut Butter Sandwich Cracker	12 oz	Box

View GS1 US FSMA Guideline Sections 3.3.3 and 4.3 >



^{*}For more information on this Local Code Value, please visit: https://www.gs1.org/standards/gdsn/3-x

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FSMA RULE 204: TOOLKIT CENTRAL

GLN and GS1 US Data Hub 10F2

- **GLNs (Global Location Numbers)** can be used to identify physical locations and streamline the sharing of Ship to, Ship From, and Traceability Lot Code Source Location Description KDEs required by FSMA Rule 204.
 - GLNs can be included in the transactional (ASNs) and event (EPCIS) data to point to the rest of the location information in a Master Data System.
 - See <u>"Connecting Master Data to Transactional and Event Data"</u> for more info.
- GS1 US Data Hub | Location can be used as a centralized source of truth for Location Description KDEs required by FSMA Rule 204.
 - Access can be given to trading partners and/or U.S. FDA as needed.



Using GLN and GS1 US Data Hub 2 OF 2

GS1 US Data Hub | Location

Click for more information on using GS1 US Data Hub I Location, Location information can be shared with U.S. FDA and/or trading partners.



Location Description KDEs

The GS1 US Global Location Number **Recommendations for FSMA Rule 204** specifies mappings between the location description KDEs defined by the U.S. FDA in the Final Rule and attributes in GLN Data Model (and GS1 US Data Hub).

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Data Attributes for Location Description KDEs

DATA ATTRIBUTES OF LOCATION DESCRIPTION	EXAMPLES OF EACH ATTRIBUTE
Business Name	Fin-to-Tail Processing Co.
Primary Phone Number	222.222.2222
Physical Location Street Address	456 Blue Water Way
City	Sarasota
State	FL
ZIP code	98765

View GS1 US FSMA Guideline Sections 3.1.3 and 4.4 >

View GS1 US GLN Recommendations for FSMA Rule 204 ▶



Advance Ship Notice (EDI 856) 1 OF 2

The EDI 856 or ASN can be used to capture and share the Shipping KDEs required by FSMA Rule 204 efficiently, regardless of the Electronic Data Interchange (EDI) version a company's system is on.

- ASNs should be used in conjunction with the Serial Shipping Container Code (SSCC) encoded in a GS1 Logistics Label for each pallet or logistics unit being delivered.
- ASNs should arrive prior to the physical pallets so the system can recognize them once that pallet SSCC is scanned.

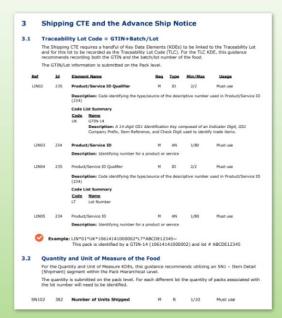




^{*}Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information, visit x12.org/products/transaction-sets

Using ASNs 2 OF 2





ASNs are commonly used to share shipping KDEs between trading partners.

> View GS1 US EDI* Recommendations for FSMA Rule 204 CTEs▶

View Food Industry Guidance for Streamlining Your Logistics Labels >

*Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information, visit x12.org/products/transaction-sets



EPCIS 1 OF 2

Electronic Product Code Information Services (EPCIS) can be used to capture and share all the FSMA Rule 204 required Critical Tracking Events (CTEs).

 The food industry determined the best practice is to use EPCIS for all CTEs required by FSMA Rule 204 except the Shipping event for which ASNs are most commonly used.





Using EPCIS 2 OF 2



EPCIS is commonly used to share "event data" between trading partners.

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*Tool owned by GS1 AISBL.



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FSMA RULE 204: TOOLKIT CENTRAL

Data Carriers, ASNs, EPCIS 10F2

- The GTIN + Lot can be used to determine the Traceability Lot Code required by FSMA Rule 204. This information can be encoded in a Data Carrier such as a barcode or Radio Frequency Identification (RFID) tag.
- A GLN can be used to determine the Traceability Lot Code (TLC) Source Reference.
- The **TLC** and **TLC Source** are critical KDEs to be able to link all other CTEs together.
 - These can be included in the EPCIS events and ASN. transactions, as well as in data carriers such as barcodes or RFID tags.
- Barcodes approved for use and implemented in current general food distribution environments are largely 1D (e.g., ITF-14, GS1-128). Most scanning systems and processes are currently optimized for 1D barcodes, though 2D barcodes may offer advantages in certain scenarios.



GS1-128 Barcode

Allows for 48 characters. Linear barcode scanners are needed to capture this information. Uses GS1 element string syntax. GTIN + date + **lot** information can be included.



GS1 **DataMatrix**

Allows for up to 2,335 encoded characters. Uses less space and has error correction. Image-based scanners are needed to capture this information. Uses GS1 element string syntax (same as GS1-128). **GTIN** + date + **lot** information can be included plus the **TLC Source Reference GLN.**



RFID

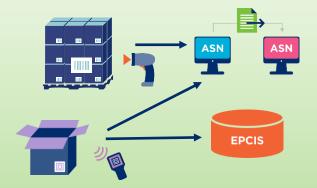
Industry participants have recently taken steps to aggressively investigate and pilot the use of the **Electronic Product Code (EPC)** in RAIN RFID tags for carton-level tracking. Such solutions provide high-speed inventory visibility without line-ofsight scanning.



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Using Data Carriers, ASNs, EPCIS 2 OF 2

TLC (GTIN + lot) & TLC Source **Reference (GLN)** are incorporated in the ASN and FPCIS events.



- They can be encoded in data carriers such as GS1 Data Matrix, RFID tags.
- GS1-128 best practice: encode GTIN, date, lot.

Sections 2.2-2.3 of the GS1 FSMA Rule 204 Guideline explain best practice to capture TLC and TLC source throughout the supply chain.

Section 3.2.2 of the GS1 FSMA Rule 204 Guideline explains the different data carriers that could be used, such as GS1-128 barcodes, 2D barcodes, and RFID tags.

View sections 2.2-2.3 and 3.2.2 of the GS1 US FSMA Rule 204 Guideline >

View North American Case Labeling Guideline for GS1-128 information >

View 2D Barcode Overview in General Distribution >

View RFID Foodservice Implementation Guideline



Connecting Master Data to Transactional and Event Data 1 OF 3

Data Framework Example

- **GS1** Identifiers act as the points connecting transactional and event data that relies on master data for context and accuracy.
- When recording a shipping transaction, transactional and event data both reference master data elements such as customer **location information** and **product details** to ensure the correctness of the transaction.

MASTER DATA TRANSACTIONAL/EVENT DATA **Product Data Location Data Event Data** Additional Identifier: GTIN®* Additional Identifier: GLN* Additional Identifiers: GTIN, GLN, SSCC* Product Name Business Name Event Date · Primary Phone Number Brand Name · Quantity & Unit of Measure · Physical Location Name Commodity Reference Records Variety · Physical Location Address • Product & Location Descriptions · Packaging Size · Growing-Area Coordinates (farm) · Traceability Lot Codes · Packaging Style Company Contact · Assignment Method Species (seafood) Phone · Point of Contact Market Name (seafood) Citv Reference Record Type State & Identifier Postal Code GDSN®/GDM* GS1 US Data Hub | Location* EPCIS/EDI*

*Denotes possible use of GS1 Standards for FSMA 204



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FSMA RULE 204: TOOLKIT CENTRAL

Connecting Master Data to Transactional and Event Data 2 OF 3

Integrate the EDI 856 with your master data systems to enhance visibility and accuracy and ensure that the relevant master data (e.g., product codes, quantities, units of measure) aligns with the shipment details in the FDI 856.

Key Steps to Master Data Integration With EDI

- 1. Mapping: Map the GS1 Identification Keys in the EDI 856 to corresponding fields in your master data system for both recipient and sender of the ASN.
- 2. Sender—ASN Creation: Generate the EDI 856 based on the actual shipment.
- 3. Receiver—Validation: Validate the EDI 856 against master data rules (e.g., product GTINs, packaging).
- **4. Receiver—Integration:** Integrate the EDI 856 with your enterprise resource planning (ERP) or warehouse management system (WMS).
- 5. Real-Time Updates: Ensure real-time updates between the EDI 856 and master data as shipments progress.

IMPORTANT: The order of the identifiers should be GTIN + batch/lot, followed by proprietary numbers.



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Connecting Master Data to Transactional and Event Data 3 OF 3

Integrate EPCIS events with your master data systems to enhance visibility and accuracy and ensure that the relevant master data (e.g., product identifiers and descriptions) aligns with the details in the EPCIS event.

Key Steps to Master Data Integration With EPCIS

- 1. Identifier Capture: Obtain TLC and TLC Source Reference identifiers (GTIN + Batch/Lot and GLN) during supply chain process.
- 2. Construct Event Data: Insert TLC and TLC Source Reference identifiers into EPCIS event data, along with date/time and other KDEs, such as source/destination GLNs.
- 3. Extract Identifiers: Obtain GS1 Identification Keys from EPCIS data exchange or internal guery. Fields to extract data from include epcClass fields, readPoint fields, source/destinationList fields.
- **4. Cross Reference:** For needed master data, cross-reference extracted identifiers from EPCIS event data to trade item and location master data management systems or other sources (GS1 US Data Hub, GDSN, etc).





Additional Resources



Beginner and Advanced Education Options

GS1 Standards Beginner Resources	•
GS1 US FSMA Rule 204 Resources and Education	•
Industry Resources	•
Investment Considerations	•
GS1 US Channel Partner Program	•



GS1 Standards Beginner Resources



View A Guide to GS1 Standards Adoption for Supply Chain Visibility >

View the GS1 US Learning Management System for training on GS1 Company Prefixes, GTINS, RFID, and more! >

View Quick Start Guide on GS1 Company Prefix Video >

View Introduction to GTIN Guideline ▶

View How RFID Benefits the Supply Chain Video ►

View Using EPCIS for Supply Chain Visibility Webinar (fee) ▶



GS1 US FSMA Rule 204 Resources and Education

FREE

GS1 Standards for FSMA Rule 204 Microlearning ▶

Informational module on GS1 Standards that can help you prepare to meet the requirements.

FREE

GS1 Standards for FSMA Rule 204 Guidance >

- Application of GS1 Standards for FSMA Rule 204 Guideline
- EDI Recommendations for FSMA Rule 204
- EPCIS Recommendations for ESMA Rule 204

Readiness Checklist for FSMA Rule 204 ▶

Understand who in your organization to involve, what steps are needed, and what resources are available.

FOR FEE

FSMA Rule 204 E-Learning Course ▶

For those familiar with GS1 Standards. this self-paced on-demand module walks you through an example of how a company uses GS1 Standards to help meet FSMA Rule 204 requirements.

FREE

Frequently Asked Questions on FSMA Rule 204 >

These FAOs provide an overview of the final Food Safety Modernization Act (FSMA), Section 204(d), and information on how GS1 Standards can help your company meet the requirements.

FOR FEE

FREE

GS1 Standards for Traceability Certificate Course >

For those **new to GS1 Standards**, learn best practices for case-level traceability and how to implement them. Receive professional credential upon completion. Bonus content included: FSMA Rule 204 & EPCIS e-Learning Module.

To get more information on X12 licensing, visit: https://x12.org/products/licensing-program



NEXT►

FSMA RULE 204: ADDITIONAL RESOURCES

Industry Resources

U.S. FDA Resources

- Final Rule
- Supply Chain Examples

Partners

- PTI FSMA Rule 204 Electronic Sortable Spreadsheet Templates (2024)
- FMI Traceability Resources
 - Implementation Guide
- NFI Resources

Traceability Case Studies

- Fish Mongers Achieves Traceability & Empowers Farmers Using GS1 Standards **Based-Solution**
- Culinary Collaborations Tracks an Ocean of Data While Preparing for FSMA 204
- CKE Restaurants Trace Food from Farm to Drive-Thru
- IPC/Subway Delivers the Promise of End-to-End Traceability Throughout the Subway System

Investment **Considerations**

The food industry compiled key investments to be considered for your customers' traceability program implementation.



Investment Considerations





GS1 US Channel Partner Program

- Give customers direct access to Global Trade
 Item Numbers (GTINs) and Global Location
 Numbers (GLNs) at the most critical point of implementation to meet the requirements of new regulations.
- Support smaller operations that are unsure with how to comply with FSMA, are new to traceability, and/or are concerned about money and manpower to comply.
- Collect reward fees on single GTINs/GLNs or GS1
 Company Prefixes of up to 1,000 capacity that were sourced within your environment.



RESOURCES >



How It Works

- **GS1 US Channel Partner Program** gives customers direct access to GS1 **identifiers** in your environment through URL links or API integration
- Add links to **meet the customer where** they are (landing page, blogs, resource pages, etc.)
- All identifiers licensed through program are added to GS1 Database

View More Information on the GS1 US Channel Partner Program





GS1 Glossary

- EDI 856/ASN: Electronic Data Interchange 856/Advance Ship Notice
- **EPCIS:** Flectronic Product Code Information Services
- GDSN®: Global Data Synchronization Network™
- GLN: Global Location Number
- GTIN®: Global Trade Item Number®

- Logistic Units: An item of any composition that is established for transport and/or storage that needs to be managed through the supply chain. These AIs are generally seen on a GS1 Logistic Label.
- **SSCC:** Serial Shipping Container Code
- **Trade Items:** Any product or service where there is a need to retrieve predefined information about it and it may be priced, ordered, or invoiced at any point in the supply chain.



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*If applicable





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